

**K902446 DISPOSABLE STERILE TABLE TOP COVER FOR HYDRADJUST**Aug 10, 1990  
70 days to decisionK902446 · Product code: **FMW** · General Hospital  
Source: <https://www.510kdatabase.net/k902446/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cover, Mattress (medical Purposes) (FMW)
Date received	Jun 1, 1990
Decision date	Aug 10, 1990
Days to decision	70 days
Third-party review	No

**APPLICANT**

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Company	<b>Mallinckrodt Group, Inc.</b>
Location	Mchenry, IL, US
Contact	THOMAS F DONOHUE
Website	<a href="https://www.mallinckrodt.com">https://www.mallinckrodt.com</a>
510(k) history	27 submissions · 27 cleared · 1976-1995

Mallinckrodt Group, Inc. is a pharmaceutical and medical device company based in McHenry, US. Now part of a restructured corporate family following a 2025 merger and subsequent spin-off, the company's regulatory history reflects its historical role in medical device manufacturing. Mallinckrodt received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company's cleared devices span radiology, cardiovascular, gastroenterology, and surgical specialties, with clearances issued between 1976 and 1995. This regulatory record is now historic...

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